

REMARKS

Claims 1-4, 6-15, 17-23, and 25 are pending in the present application. Claims 5, 16, and 24 have been withdrawn without disclaimer of or prejudice to the subject matter therein.

37 C.F.R. § 1.83 and 35 U.S.C. § 132

Fig. 5 has been modified to more clearly show the grooved ribbed or notched material that may comprise the inflated balloon. Modified Fig. 5 is being submitted for consideration via a substitution of drawings being filed concurrently herewith. The undersigned submits that this modified Fig. 5 is not new material. The original specification contemplates various characteristics of the balloon and provides as an example that the balloon may be internally ribbed or notched or otherwise specifically configured to increase its deformability. *See* Specification, pg. 5, lines 10-11. Consequently, the undersigned respectfully requests withdrawal of these objections.

35 USC § 112

The Office Action rejects claim 19 under 35 U.S.C. 112, second paragraph, contending that claim 19 “is vague because it is unclear about what applicant intended by a grooved material.” The undersigned submits that grooved materials are provided for in the original specification as the original specification contemplates various characteristics of the balloon and provides as an example that the balloon may be internally ribbed or notched or otherwise specifically configured to increase its deformability. *See* Specification, pg. 5, lines 10-11. Consequently, the undersigned respectfully requests withdrawal of this objection.

35 U.S.C. §§ 102 and 103

Each of the pending claims stand rejected as allegedly anticipated by or obvious in light of five different US patents. The undersigned submits that each of these five cited references each fail to disclose or suggest “a first inflatable balloon (or membrane) having a measurable elasticity ... a dilation bladder located within the first inflatable balloon (or membrane) ... the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder,” as substantially recited in independent claims 1, 12, and 20. For at least this reason, the undersigned submits that these claims and their dependent claims (nos. 2-4, 6-11, 13-15, 17-19, 21-23, and 25) are patentable over the cited art.

As to Abiuso et al. (U.S. Patent No. 5,213,576), entitled “Therapeutic Porous Balloon Catheter,” the undersigned submits that the balloons in Abiuso have the same elasticity and that Abiuso does not suggest or disclose providing balloon and bladders having different elasticities as recited in the claims. *See e.g.*, col. 2, lns. 39-47; co; 3 lns. 30-35; Fig. 4.

CONCLUSION

The undersigned requests further consideration and allowance of the pending claims.

The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

A paper entitled "Markings to Show Changes Made," is attached.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. Grasso', written over a horizontal line.

Fred T. Grasso
(Reg. No. 43,644)

Dated: November 25, 2002

1500 K Street, N.W., Suite 700
Washington, DC 20005
Tel: (202) 220-4200
Fax: (202) 220-4201

MARKINGS TO SHOW CHANGES MADE

1. (Twice amended) A system for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a source of fluid in communication with the internal lumen of the catheter; and

a first inflatable balloon having an exterior surface,

the first inflatable balloon in communication with the internal lumen of the catheter,

the first inflatable balloon [being hyper-deformable such that in an expanded state the first inflatable balloon replicates the irregular interior vessel surface] having a measurable elasticity, [and]

the exterior surface of the first inflatable balloon in communication with a therapeutic when the first inflatable balloon is in an expanded state; and a dilation bladder located within the first inflatable balloon,

the dilation bladder in fluid communication with the second internal lumen of the catheter by way of a plurality of dilation bladder openings in the catheter,

the dilation bladder deformable from a non-inflated position to an inflated position,

the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder.

5. Withdrawn

12. (Twice Amended) A device for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a [hyper-deformable] first inflatable balloon in fluid communication with the internal lumen of the catheter,

the [hyper-deformable] first inflatable balloon [adapted to replicate the irregular interior vessel surface when the balloon is in an expanded state] having a measurable elasticity,

the [hyper-deformable] first inflatable balloon having an exterior surface and an interior surface;

[a source of fluid in fluid communication with the internal lumen; and
a fluid pump in fluid communication with the source of fluid.] and
a dilation bladder located within the first inflatable balloon. ^a
the dilation bladder in fluid communication with the second internal lumen of
the catheter by way of a plurality of dilation bladder openings in the catheter,
the dilation bladder deformable from a non-inflated position to an inflated
position,
the dilation bladder having a measurable elasticity, the elasticity of the first
inflatable balloon being greater than the elasticity of the dilation bladder.

13. (Twice Amended) The device of claim 12 wherein a surface of the [hyper-deformable] first inflatable balloon contains grooves sized to increase the deformability of the inflatable balloon.

14. (Amended) The device of claim 12 further comprising:
a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the [hyper-deformable] first inflatable balloon.

15. (Amended) The device of claim 14 wherein the therapeutic traverses through the [hyper-deformable] first inflatable balloon before the therapeutic contacts the exterior surface of the [hyper-deformable] first inflatable balloon.

16. Withdrawn

17. (Amended) The system of claim 1[6]2 further comprising:
a second internal lumen within the catheter,
the second internal lumen passing through the [hyper-deformable] first
inflatable balloon, the [hyper-deformable] first inflatable balloon positioned around
the second internal lumen,

the second internal lumen having an entrance orifice and an exit orifice,
the entrance orifice positioned upstream of the [hyper-deformable] first
inflatable balloon, upstream relative to a fluid flowing through the irregular interior
vessel, and the exit orifice positioned downstream of the [hyper-deformable] first
inflatable balloon, downstream relative to fluid flowing through the irregular interior
vessel.

18. (Amended) The device of claim 12 further comprising:

a second balloon positioned between the dilation bladder and the [hyper-deformable]
first inflatable balloon, the second balloon having an outside surface, the outside surface in
communication with therapeutic.

19. (Twice Amended) The device of claim 12 wherein the [hyper-deformable] first
inflatable balloon is made with a grooved material.

20. (Twice Amended) A method for delivering therapeutic to an irregular interior vessel
surface of a patient comprising:

inserting an expandable [hyper-deformable] first membrane attached to a catheter into
the vessel of the patient, the expandable [hyper-deformable] first membrane having an
exterior surface and a measurable elasticity;

positioning the expandable [hyper-deformable] first membrane at the irregular interior
vessel surface within the patient; [and]

forcing a fluid into the expandable [hyper-deformable] first membrane to expand the
expandable [hyper-deformable] first membrane, the expandable [hyper-deformable] first
membrane becoming juxtaposed to and replicating the irregular interior surface of the vessel
of the patient; and,

after positioning the expandable first membrane at the irregular interior surface of the
vessel within the patient, inflating a dilation bladder located within the expandable first
membrane,

the dilation bladder having a measurable elasticity, the elasticity of the first
inflatable balloon being greater than the elasticity of the dilation bladder.

21. (Amended) The method of claim 20 wherein the exterior surface of the expandable [hyper- deformable] first membrane is in communication with a therapeutic.
22. (Amended) The method of claim 20 further comprising:
pushing a therapeutic over the exterior surface of the expandable [hyper-deformable] first membrane after the expandable [hyper-deformable] first membrane is positioned at the irregular interior surface of the vessel.
23. (Amended) The method of claim 22 wherein the therapeutic is pushed through the expandable [hyper-deformable] first membrane to reach the exterior surface of the expandable [hyper-deformable] first membrane and wherein the fluid is a tracing fluid.
24. Withdrawn.
25. (Amended) The method of claim 20 further comprising:
opening an entrance orifice of a passage traversing the expandable [hyper-deformable] first membrane, the passage compatible with the fluid flowing within the vessel of the patient's body.